Improving Public Health:
Promoting Safe and Effective Drug Use

FDA's Center for Drug Evaluation and Research (CDER) promotes and protects the health of Americans by assuring that all prescription and over-the-counter drugs are safe and effective. CDER evaluates all new drugs before they are sold, and serves as a consumer watchdog for the more than 10,000 drugs on the market to be sure they continue to meet the highest standards. The center routinely monitors TV, radio, and print drug ads to ensure they are truthful and balanced. CDER also plays a critical role in providing health professionals and consumers information to use drugs appropriately and safely. Recent drug approvals represent important advances for children, women, elderly persons, and patients with heart disease and cancer, leading causes of death in the United States. CDER priorities include:

Assuring that safe and effective new and generic drugs are available to the American public

- CDER's multidisciplinary scientific staff conducts thorough reviews of all new and generic drugs.
- FDA has reduced the average review time for new drugs covered under the Prescription Drug User Fee Act (PDUFA) from more than 2.5 years to less than one year.
- Patients with life-threatening illnesses gain access to treatments sooner.
- FDA has finalized regulations that require many drug manufacturers to provide information on how children can take their drugs safely and effectively.

Improving drug safety

- After approval, CDER identifies drug safety concerns through voluntary reports submitted to the FDA's MedWatch program and the center's adverse event reporting system, which together receive more than 250,000 reports each year.
- CDER scientists analyze adverse event reports and take actions that best protect the public's health, ranging from providing more information to patients to withdrawing drugs from the marketplace.
- CDER has instituted a comprehensive program to communicate with consumers and improve patient safety. For example, 6 million consumers received FDA's brochure on proper medication use.
- FDA works with industry to reduce errors related to confusing packaging and/or drug names.
- FDA has proposed a regulation to make prescription drug labeling easier for health-care providers to use.

Year 2000 Drug Approvals

In the year 2000, FDA approved 27 new molecular entities (products with ingredients never marketed before in the United States) in the median time of 15.6 months. CDER approved 98 original new drugs in a median time of 11.2 months, including 20 priority products that offered a significant therapeutic advantage. CDER approved 244 generic counterparts of original drugs, one per business day on average.

For more information, please contact CDER at 301-827-4573, or visit FDA's Web site at *www.fda.gov/cder.*

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